

LISTING OF THE CLAIMS

1. (Original) A flavored dosage form comprising a sustained release wet matrix of ethylcellulose and a flavoring agent selected from essential oils, constituents of essential oils, and mixtures thereof, wherein, in an aqueous environment, the matrix gradually releases the flavoring agent over a time period of at least 15 minutes.
2. (Original) The dosage form of claim 1, wherein the weight ratio of the hydrophilic polymer to the flavoring agent is selected to provide sustained release of the flavoring agent over a time period of about 15 minutes to about 60 minutes.
3. (Original) The dosage form of claim 2, wherein the weight ratio of the hydrophilic polymer to the flavoring agent is selected to provide sustained release of the flavoring agent over a time period of at least 60 minutes.
4. (Original) The dosage form of claim 3, wherein the weight ratio of the hydrophilic polymer to the flavoring agent is selected to provide sustained release of the flavoring agent over a time period of at least 2 hours.
5. (Original) The dosage form of claim 1, wherein the ethylcellulose has a solution viscosity in the range of approximately 1 to 120 cP as determined at 25 °C using a 5 wt.% aqueous solution.
6. (Original) The dosage form of claim 5, wherein the solution viscosity is in the range of approximately 3 to 100 cP.
7. (Original) The dosage form of claim 6, wherein the solution viscosity is in the range of approximately 6 to 49 cP.
8. (Original) The dosage form of claim 1, wherein the flavoring agent is an essential oil.

9. (Original) The dosage form of claim 8, wherein the essential oil imparts a food flavor.
10. (Original) The dosage form of claim 9, wherein the essential oil is a citrus oil.
11. (Original) The dosage form of claim 10, wherein the citrus oil is selected from lemon oil, lime oil, neroli oil, orange oil, and combinations thereof.
12. (Original) The dosage form of claim 9, wherein the essential oil is a mint oil.
13. (Original) The dosage form of claim 12, wherein the mint oil is peppermint oil, spearmint oil, or a combination thereof.
14. (Original) The dosage form of claim 9, wherein the essential oil is selected from anise oil, cardamom oil, cinnamon oil, clove oil, coriander oil, eriodictyon fluidextract, eucalyptus oil, fennel oil, glycyrrhiza extract, lemongrass oil, nutmeg oil, and combinations thereof.
15. (Original) The dosage form of claim 1, wherein the flavoring agent is a constituent of an essential oil.
16. (Original) The dosage form of claim 15, wherein the flavoring agent is selected from terpenes, sesquiterpenes, and combinations thereof.
17. (Original) The dosage form of claim 16, wherein the flavoring agent is a terpene.
18. (Original) The dosage form of claim 17, wherein the terpene is selected from *d,l*-camphene, *d*-camphene, *l*-camphene, Δ^3 -carene, *trans*- β -ocimene, *cis*- β -ocimene, *trans*- α -ocimene, *cis*- α -ocimene, β -pinene, β -phellandrene, α -terpinene, β -terpinene, γ -terpinene, and combinations thereof.

19. (Original) The dosage form of claim 16, wherein the flavoring agent is a sesquiterpene.

20. (Original) The dosage form of claim 19, wherein the sesquiterpene is selected from α -cadinene, β -cadinene, α -caryophyllene, copaene, β -farnesene, isocaryophyllene, ylangene, and combinations thereof.

21. (Original) The dosage form of claim 15, wherein the flavoring agent is an organic acid, an alcohol, an aldehyde, a ketone, an ester, a phenyl ether, or a mixture thereof.

22. (Original) The dosage form of claim 21, wherein the flavoring agent is selected from *p*-anisic acid, cinnamic acid, phenylacetic acid, *d,l*-borneol, *d*-borneol, *l*-borneol, carvacrol, chavicol, cinnamyl alcohol, linalool, menthol, nerolidol, nerol, *d,l*- α -terpineol, *d*- α -terpineol, *l*- α -terpineol, thymol, acetaldehyde, anisaldehyde, cinnamaldehyde, benzaldehyde, citral, isovaleric aldehyde, piperonal, salicylaldehyde, valeric aldehyde, vanillin, carvone, jasmone, menthone, piperitone, amyl acetate, bornyl acetate, benzyl benzoate, butyl cinnamate, cinnamyl anthranilate, geranyl acetate, linalyl acetate, menthyl acetate, menthyl isovalerate, methyl salicylate anethole, eugenol, safrol, estragole, and combinations thereof.

23. (Original) The dosage form of claim 1, wherein the weight ratio of the hydrophilic polymer to the flavoring agent is in the range of approximately 1:5 to 2:1.

24. (Original) The dosage form of claim 23, wherein the weight ratio is in the range of approximately 1:2 to 1.5:1.

25. (Original) The dosage form of claim 24, wherein the weight ratio is in the range of approximately 1:1.5 to 1.5:1.

26. (Original) The dosage form of claim 1, further including an effective sweetening amount of a sweetener selected from a sugar, a non-sugar sweetening agent, or a mixture thereof.

27. (Original) The dosage form of claim 26, wherein the sweetener is a sugar.
28. (Original) The dosage form of 26, wherein the sweetener is a non-sugar sweetening agent.
29. (Original) The dosage form of claim 28, wherein the non-sugar sweetening agent is selected from aspartame, saccharin, sodium saccharin, calcium saccharin, sucralose, acesulfame-K, sorbitol, xylitol, steviosin, steviol, mannitol, erythritol, lactitol, and mixtures thereof.
30. (Original) The dosage form of claim 1, comprising a lozenge.
31. (Original) The dosage form of claim 1, further including an amount of a gum base effective to provide the dosage form as a chewing gum.
32. (Original) The dosage form of any one of claims 1, 30, and 31, further comprising an effective amount of a beneficial agent in addition to the flavoring agent.
33. (Original) The dosage form of claim 32, wherein the beneficial agent is a source of Zn^{2+} .
34. (Original) The dosage form of claim 33, wherein the beneficial agent is selected from zinc gluconate, acetate, chloride, propionate, butyrate, *n*-butyrate, β -hydroxybutyrate, benzoate, formate, and sulfate.
35. (Original) The dosage form of claim 34, wherein the beneficial agent is selected from zinc gluconate and zinc acetate.
36. (Original) The dosage form of claim 33, further comprising at least one additional agent for treating the common cold.

37. (Original) The dosage form of claim 36, wherein the at least one additional agent is vitamin C.

38. (Original) The dosage form of claim 32, wherein the beneficial agent is a local anesthetic agent.

39. (Original) The dosage form of claim 32, wherein the beneficial agent is a local antibiotic.

40. (Original) The dosage form of claim 32, wherein the beneficial agent is a diet aid.

41. (Original) The dosage form of claim 40, wherein the diet aid is selected from 5-hydroxytryptophan, tyrosine, phenylalanine, pseudoephedrine, ephedrine, phenylpropanolamine, chromium picolinate, aspirin, caffeine, and combinations thereof.

42. (Original) The dosage form of claim 40, wherein the diet aid is an herbal mixture or extract thereof.

43. (Original) The dosage form of claim 41, wherein the diet aid is selected from guarana and ma huang.

44. (Original) The dosage form of claim 32, wherein the beneficial agent is a source of fluoride ion.

45. (Original) The dosage form of claim 32, wherein the beneficial agent is nicotine.

46. (Original) The dosage form of claim 1, further comprising a colorant.

47. (Currently amended) The dosage form of claim 30, further including at least one additive selected from binders, release rate accelerants, release rate retardants, adhesion-

increasing agents, adhesion-reducing agents, flavor stabilizers, flavor diluents, pH-adjusting agents, preservatives, lubricants, and fillers.

48. (Original) A flavored lozenge comprising at least one biocompatible, water-insoluble, hydrophilic polymer and a flavoring agent effective to provide a sustained release wet matrix upon admixture with said at least one polymer, wherein the flavoring agent is selected from essential oils, constituents of essential oils, and mixtures thereof, and further wherein the lozenge provides for sustained release of the flavoring agent in the mouth over a time period of at least 15 minutes.

49. (Original) The lozenge of claim 48, wherein said at least one biocompatible, water-insoluble, hydrophilic polymer comprises a lactic acid polymer.

50. (Original) The lozenge of claim 49, wherein the lactic acid polymer is a homopolymer selected from poly(D,L-lactic acid), poly(D-lactic acid), poly(L-lactic acid), and mixtures thereof.

51. (Original) The lozenge of claim 49, wherein the lactic acid polymer is a poly(lactide-co-glycolide) selected from poly(D,L-lactide-co-glycolide), poly(D-lactide-co-glycolide), poly(L-lactide-co-glycolide).

52. (Original) The lozenge of claim 49, wherein said at least one biocompatible, water-insoluble hydrophilic polymer further comprises a water-soluble cellulosic polymer.

53. (Original) The lozenge of claim 51, wherein said at least one biocompatible, water-insoluble hydrophilic polymer further comprises a water-soluble cellulosic polymer.

54. (Original) The lozenge of claim 52 or claim 53, wherein the cellulosic polymer is selected from methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, and combinations thereof.

55. (Original) The lozenge of claim 48, further including an effective sweetening amount of a sweetener selected from a sugar, a non-sugar sweetening agent, or a mixture thereof.

56. (Original) The lozenge of 55, wherein the sweetener is a non-sugar sweetening agent.

57. (Original) The lozenge of claim 56, wherein the non-sugar sweetening agent is selected from aspartame, saccharin, sodium saccharin, calcium saccharin, sucralose, acesulfame-K, sorbitol, xylitol, steviosin, steviol, mannitol, erythritol, lactitol, and mixtures thereof.

58. (Original) The lozenge of claim 48, further comprising an effective amount of a beneficial agent in addition to the flavoring agent, and wherein the lozenge additionally provides for sustained release of the beneficial agent in the mouth over a time period of at least 15 minutes.

59. (Original) The lozenge of claim 58, wherein the beneficial agent is a source of Zn^{2+} .

60. (Original) The lozenge of claim 59, wherein the beneficial agent is selected from zinc gluconate, acetate, chloride, propionate, butyrate, *n*-butyrate, β -hydroxybutyrate, benzoate, formate, and sulfate.

61. (Original) The lozenge of claim 60, wherein the beneficial agent is selected from zinc gluconate and zinc acetate.

62. (Original) The lozenge of claim 59, further comprising at least one additional agent for treating the common cold.

63. (Original) The lozenge of claim 62, wherein the at least one additional agent is vitamin C.

64. (Original) The lozenge of claim 58, wherein the beneficial agent is a topical anesthetic agent.

65. (Original) The lozenge of claim 58, wherein the beneficial agent is a topical anti-infective agent.

66. (Original) The lozenge of claim 58, wherein the beneficial agent is a diet aid.

67. (Original) The lozenge of claim 66, wherein the diet aid is selected from 5-hydroxytryptophan, tyrosine, phenylalanine, pseudoephedrine, ephedrine, phenylpropanolamine, chromium picolinate, aspirin, caffeine, and combinations thereof.

68. (Original) The lozenge of claim 67, wherein the diet aid is an herbal mixture or extract thereof.

69. (Original) The lozenge of claim 68, wherein the diet aid is selected from guarana and ma huang.

70. (Original) The lozenge of claim 60, wherein the beneficial agent is a source of fluoride ion.

71. (Original) The lozenge of claim 60, wherein the beneficial agent is nicotine.

72. (Original) The lozenge of claim 48, further comprising a colorant.

73. (Currently amended) The lozenge of claim 48, further including at least one additive selected from binders, release rate accelerants, release rate retardants, adhesion-increasing agents, adhesion-reducing agents, flavor diluents, pH-adjusting agents, preservatives, lubricants, and fillers.

74. (Currently amended) A flavored lozenge for sustained release of a flavoring agent, comprising an admixture of:

ethylcellulose having a solution viscosity in the range of approximately ~~6 to 49 cP~~ 1-120 cP as determined at 25 °C using a 5 wt.% aqueous solution;

a flavoring agent selected from essential oils, individual terpenes, and individual sesquiterpenes; and

a non-sugar sweetening agent,

wherein the weight ratio of the ethylcellulose to the flavoring agent is in the range of approximately 1:1.2 to 1.2:1.

75. (Original) The lozenge of claim 74, further comprising an effective amount of a beneficial agent, and wherein the lozenge additionally provides for sustained release of the beneficial agent in the mouth over a time period of at least 15 minutes.

76. (Withdrawn) A method for achieving sustained release of a flavoring agent in the mouth over a time period of at least 15 minutes, comprising administering the dosage form of claim 1 to the mouth of an individual.

77. (Withdrawn) A method for achieving sustained release of a flavoring agent in the mouth over a time period of at least 15 minutes, comprising administering the lozenge of claim 48 to the mouth of an individual.

78. (Withdrawn) A method for delivering a beneficial agent to a human individual, comprising administering the dosage form of claim 32 to the mouth of the individual.

79. (Withdrawn) A method for achieving sustained release of a beneficial agent in the mouth over a time period of at least 15 minutes, comprising administering the lozenge of claim 58 or claim 75 to the mouth of an individual.

80. (Withdrawn) The method of claim 79, wherein the beneficial agent is an ionizable zinc compound, a topical anesthetic agent, a topical anti-infective agent, a diet aid, a source of fluoride ion, or nicotine.

81. (Withdrawn and currently amended) A method for treating the common cold, comprising administering to an individual in need of such treatment a flavored lozenge comprising an admixture of:

ethylcellulose having a solution viscosity in the range of approximately ~~6 to 49 cP~~ 1 to 120 cP as determined at 25 °C using a 5 wt.% aqueous solution;

a flavoring agent selected from essential oils, individual terpenes, and individual sesquiterpenes;

an ionizable zinc compound; and

a sweetening agent,

wherein the weight ratio of the ethylcellulose to the flavoring agent is in the range of approximately 1:1.5 to 1.5:1.

82. (Withdrawn) The method of claim 81, wherein the ionizable zinc compound is zinc gluconate.

83. (Withdrawn) The method of claim 81, wherein the ionizable zinc compound is zinc acetate.

84. (Withdrawn) The method of claim 81, wherein the lozenge further comprises vitamin C.

85. (Withdrawn) The method of claim 81, wherein the weight ratio is in the range of approximately 1:1.2 to 1.2:1.

86. (Withdrawn and currently amended) A method for treating a sore throat, comprising administering to an individual in need of such treatment a flavored lozenge comprising an admixture of:

ethylcellulose having a solution viscosity in the range of approximately ~~6 to 49 cP~~ 1-120 cP as determined at 25 °C using a 5 wt.% aqueous solution;
a flavoring agent selected from essential oils, individual terpenes, and individual sesquiterpenes;
a local anesthetic agent; and
a sweetening agent,
wherein the weight ratio of the ethylcellulose to the flavoring agent is in the range of approximately 1:1.5 to 1.5:1.

87. (Withdrawn) The method of claim 86, wherein the lozenge further comprises a local anti-infective agent.

88. (Withdrawn) The method of claim 86, wherein the weight ratio is in the range of approximately 1:1.2 to 1.2:1.

89. (Withdrawn and currently amended) A method for facilitating weight loss, comprising administering to an individual in need of such treatment a flavored lozenge comprising an admixture of:

ethylcellulose having a solution viscosity in the range of approximately ~~6 to 49 cP~~ 1-120 cP as determined at 25 °C using a 5 wt.% aqueous solution;
a flavoring agent selected from essential oils, individual terpenes, and individual sesquiterpenes;
a diet aid; and
a non-sugar sweetening agent,
wherein the weight ratio of the ethylcellulose to the flavoring agent is in the range of approximately 1:1.5 to 1.5:1.

90. (Withdrawn) The method of claim 89, wherein the diet aid is selected from 5-hydroxytryptophan, tyrosine, phenylalanine, pseudoephedrine, ephedrine, phenylpropanolamine, chromium picolinate, aspirin, caffeine, and combinations thereof.

91. (Withdrawn) The method of claim 89, wherein the diet aid is an herbal mixture or extract thereof.

92. (Withdrawn) The method of claim 91, wherein the diet aid is selected from guarana and ma huang.

93. (Withdrawn) The method of claim 89, wherein the weight ratio is in the range of approximately 1:1.2 to 1.2:1.

94. (Withdrawn and currently amended) A method for assisting an individual in quitting smoking, comprising administering to an individual in need of such treatment a flavored lozenge comprising an admixture of:

ethylcellulose having a solution viscosity in the range of approximately ~~6 to 49 cP~~ 1-120 cP as determined at 25 °C using a 5 wt.% aqueous solution;

a flavoring agent selected from essential oils, individual terpenes, and individual sesquiterpenes;

nicotine; and

a sweetening agent,

wherein the weight ratio of the ethylcellulose to the flavoring agent is in the range of approximately 1:1.5 to 1.5:1.

95. (Currently amended) A flavored dosage form for delivering a beneficial agent to a mucosal surface within the mouth, the dosage form having at least one adhesive surface that serves to adhere the dosage form to the mucosal surface, wherein the dosage form comprises:

ethylcellulose having a solution viscosity in the range of approximately ~~6 to 15 cP~~ 1-120 cP as determined at 25 °C using a 5 wt.% aqueous solution;

a flavoring agent selected from essential oils, individual terpenes, and individual sesquiterpenes;

a beneficial agent; and

a sweetening agent,

wherein the weight ratio of the ethylcellulose to the flavoring agent is in the range of approximately 1:1.5 to 1.5:1.

96. (Original) The dosage form of claim 95, wherein the beneficial agent is an anti-infective agent, a local anesthetic agent, or a local anti-inflammatory agent.

97. (Withdrawn and currently amended) A method for delivering a beneficial agent to a mucosal surface within the mouth, comprising administering to an individual in need of such treatment a flavored dosage form having at least one adhesive surface that serves to adhere the dosage form to the mucosal surface, and comprising:

ethylcellulose having a solution viscosity in the range of approximately ~~6 to 15 cP~~ 1-120 cP as determined at 25 °C using a 5 wt.% aqueous solution;

a flavoring agent selected from essential oils, individual terpenes, and individual sesquiterpenes;

a beneficial agent; and

a sweetening agent,

wherein the weight ratio of the ethylcellulose to the flavoring agent is in the range of approximately 1:1.5 to 1.5:1.

98. (Withdrawn) The method of claim 97, wherein the beneficial agent is an anti-infective agent, a local anesthetic agent, or a local anti-inflammatory agent.

99. (Withdrawn) A taste-masked formulation for administration of a beneficial agent in the oral cavity, comprising a coated, granulated mixture of the beneficial agent, at least one biocompatible, water-insoluble, hydrophilic polymer, and a flavoring agent effective to provide a sustained release wet matrix upon admixture with said at least one polymer, wherein the flavoring agent is selected from essential oils, constituents of essential oils, and mixtures thereof.